APR 1 6 2014

510(k) Summary
for the INTESS™ Cervical Cage

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the INTESS™ Cervical Cage

1. GENERAL INFORMATION

Date Prepared: April 10, 2014

Trade Name: INTESS™ Cervical Cage

Common Name: intervertebral body fusion device

Classification Name: Intervertebral body fusion device – cervical

Class: II

Product Code: ODP

CFR section: 21 CFR section 888.3080

Device panel: Orthopedic

Legally Marketed Predicate Device: Spinal Elements, Crystal Cervical Cage (K073351)
Zimmer, BAK/C Vista Interbody Fusion (P980048 S3)
LDR Spine Cervical Interbody Fusion System (K091088)
Daytona Anterior Cervical Cage System (K110733)

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2. DEVICE DESCRIPTION

The INTESS™ Cervical Cage was developed as implants for the stabilization of the cervical column. The INTESS™ implants have graft windows which help facilitate bony integration. The INTESS™ implants have ridges on both their inferior and superior surfaces. X-ray markers are integrated for visualization of the implants during and after surgery.

Materials:

Zeniva ZA500 PEEK conforming to ASTM F2026.
Unalloyed tantalum conforming to ASTM F560.

Function:

Maintain adequate disc space until fusion occurs.

3. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

The INTESS™ Cervical Cage is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.

4. INTENDED USE

The INTESS™ Cervical Cage is intended for anterior interbody spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one disc level (C2-T1). Cervical degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. This device is intended for use with supplemental internal fixation systems and autogenous bone graft implanted via an open, anterior approach. Patients should have at least six weeks of non-operative treatment prior to treatment with intervertebral cage.

5. NON-CLINICAL TEST SUMMARY

The following tests were conducted:

- Static and dynamic compression per ASTM F2077
- Static and dynamic torsion per ASTM F2077
- Subsidence per ASTM F2267

The results of this testing indicate that the INTESS™ Cervical Cage is equivalent to predicate devices.

6. CLINICAL TEST SUMMARY

No clinical studies were performed

7. CONCLUSIONS NONCLINICAL AND CLINICAL

Kalitec Direct, LLC considers the INTESS™ Cervical Cage to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 16, 2014

Kalitec Direct, LLC
% The OrthoMedix Group, Incorporated
Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K133815
Trade/Device Name: INTESS™ Cervical Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: January 21, 2014
Received: January 23, 2014

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133815

Device Name

INTESS™ Cervical Cage

Indications for Use *(Describe)*

The INTESS™ Cervical Cage is intended for anterior interbody spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one disc level (C2-T1). Cervical degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. This device is intended for use with supplemental internal fixation systems and autogenous bone graft implanted via an open, anterior approach. Patients should have at least six weeks of non-operative treatment prior to treatment with intervertebral cage.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

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